[2011] [OP0288] TREATMENT OF POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS FOR 5 YEARS WITH DENOSUMAB: TWO-YEAR RESULTS FROM THE FREEDOM TRIAL EXTENSION

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Background: The open-label extension of the pivotal, 3-year, phase 3 FREEDOM trial evaluates the long-term efficacy and safety of denosumab (DMAb) for up to 10 years in postmenopausal women with osteoporosis.
Objectives: Report results from the first 2 years of the extension, representing up to 5 continuous years of DMAb treatment.
Methods: All women who completed FREEDOM were invited to participate in the extension. During the extension, all women receive 60 mg DMAb sc every 6 months and daily calcium and vitamin D. For those given DMAb during FREEDOM, the data reflect 5 years of DMAb (long-term group). For those given placebo during FREEDOM, the data reflect 2 years of DMAb (de novo group).
Results: A total of 4550 (70.2%) women who completed FREEDOM enrolled in the extension (2343 long-term; 2207 de novo). The long-term group had additional 1.9% and 1.7% yearly lumbar spine BMD increases and 0.7% and 0.6% yearly total hip BMD increases during the 4th and 5th years of DMAb treatment (all $P<0.0001$ compared with extension baseline). With 5 years of DMAb, the total BMD increase reached 13.7% (lumbar spine) and 7.0% (total hip). BMD increases during the first 2 years of DMAb treatment in the de novo group were 7.9% and 4.1% at the lumbar spine and total hip (all $P<0.0001$ compared with extension baseline). Similar rapid and large reductions in serum CTX were observed in both groups following DMAb administration, with attenuation at the end of the dosing interval, as previously described.[1] In both groups, yearly incidences of new vertebral and nonvertebral fractures were low and below the rates observed in the FREEDOM placebo group. Adverse events (AEs) and serious AEs did not increase over 5 years of DMAb treatment. For 2 subjects in the de novo group, an oral AE was adjudicated to ONJ. Both cases healed completely and without further complications; one subject continues to receive DMAb. There were no atypical femoral fractures.
Conclusions: Long-term (up to 5 years) DMAb treatment of postmenopausal women with osteoporosis remained well-tolerated and continued to significantly decrease serum CTX and increase BMD.
References:

1. Eastell; JBMR, 2010; DOI-10.1002/jbmr.251

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